

April 17, 2003

Via Fax & Overnight Mail

Mr. Thomas L. Morrison
California Building Standards Commission
2525 Natomas Park Drive, Suite 130
Sacramento, CA 95833-2936

RE: Appeal of denial for a Code Change to the California Medical Code Section 408.4-1
Filters for Outpatient Clinics

Dear Mr. Morrison:

This is to inform you of Fresenius Medical Care's appeal of the February 20, 2003 denial of its Code Change Petition relating to the requirement for 90% air filter banks in outpatient hemodialysis clinics. Copies of the November 29, 2002 Code Change Petition and the February 20, 2003 letter of denial are enclosed.

The reason for denial stated in the February 20, 2003 letter is based upon criteria of Section 1-806 (b) and (e) of Title 24.

Please allow Fresenius Medical Care to respond to the stated reasons for denial:

1. Item (e) "The issues cited by the petitioner are factually incorrect"

In stating that the issues cited by petitioner are "factually incorrect," the February 20 letter appears to take issue with Fresenius Medical Care's reliance on the footnote to the American Institute of Architects Guidelines for Design and Construction of Hospital and Health Care Facilities Table 9.1 as the basis for the petition for the code change. Respectfully, Fresenius Medical Care's reliance on the footnote is proper and the issues are "factually correct." The footnote provides an exception to the 90% air filtration requirement and was added to the ATA Guidelines as a direct result of Fresenius Medical Care's request to the ATA to exempt outpatient hemodialysis clinics.

The February 20 letter also appears to contend that the issues are "factually incorrect" because hemodialysis clinics are not "'primary' outpatient facilities" that would fall within the exception to the 90% air filtration requirement. Respectfully, hemodialysis clinics do fall within the second part of the exception to the 90% air filtration requirement, i.e. "outpatient facilities that do not perform invasive applications or procedures." No invasive applications or-procedures are performed in hemodialysis clinics.

The February 20 letter also references the AIA Guidelines 9.1.A which states that hemodialysis clinics have needs that are not addressed in these Guidelines and that they must meet and satisfy additional conditions to meet respective programs. The February 20 letter does not say what those additional conditions are, but no other state has interpreted those "additional conditions" to mean 90% air filters.

Z. Item (e) "Resolving the issue raised by the petitioner would compromise the agency's ability to carry out its legal mandate."

The denial states that State of California is concerned for the "health & safety of some patients, specifically those inpatients who are treated in a free standing outpatient clinic..." None of Fresenius Medical Care's outpatient clinics treat hospital inpatients, and to Fresenius Medical Care's knowledge, no competitors who operate outpatient hemodialysis clinics treat hospital inpatients.

In summary, the AIA Guidelines have made an exception to the 90% filters for outpatient clinics that do not perform invasive procedures. As no invasive procedures are performed in hemodialysis clinics, the Code should be amended to make an exception to the 90% air filter requirement for hemodialysis clinics. Additionally, hospital inpatients are not treated in outpatient hemodialysis clinics. Finally, none of the other 40-plus states in which Fresenius Medical Care operates hemodialysis clinics requires the 90% filters. The requirement to install these filters is adding unnecessary cost to the construction and operation of hemodialysis clinics and is contributing to the overall increase in health care costs in California.

We thank you for considering this appeal. I will be happy to answer any of your questions.
Sincerely,

FRESENIUS MEDICAL CARE NORTH AMERICA

William A. Previdi
Vice President - FDMS

WAP/hdr

CC: Domenic Gaeta
Fali Sidhva
Chris Egan
Rick Duckworth